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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,811	05/22/2001	David A. White	12553-009215	3520

20350 7590 12/30/2003

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/30/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,811

Applicant(s)

WHITE ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 18-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 18-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2003 and 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 8, 2003. The Examiner acknowledges the amendments to claims 11-13 and 18-38. Claims 11-13 and 18-38 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11-13, 18, 20-22, 25-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soltesz ('925) in view of Pomeranz ('609).

Soltesz teaches an intravascular catheter with variable flexibility properties. The catheter has a single lumen for guiding a secondary catheter device. The catheter includes a catheter body including a proximal tubular portion 505; an intermediate tubular portion 515 of a transitional material; and a distal tubular portion 520. The intermediate tubular portion is disposed between the proximal and distal portions and has a higher flexural modulus than the distal tubular portion and a lower flexural modulus than the proximal portion. The portions are thermally bonded. The proximal portion, intermediate portion, and distal portion can be formed of a plastic or polymer material including polyurethanes, polyesters or silicone, polyimides, nylons, polyethylenes, polypropylenes, and polytetrafluoroethylene (PTFE) (col. 3, lines 3-7).

The intermediate portion has an exemplary flexural modulus of 60 to 100 kpsi and an exemplary length of 70 mm; however, the lengths and flexural modulus of all three portions may be varied as a design choice. Soltesz teaches all of the limitations of the claims except that the secondary device is an imaging catheter including a drive cable.

Pomeranz teaches a guidewire imaging catheter including drive cable for rotating a work element of a imaging catheter. The guidewire imaging catheter is adapted to be used as an imaging catheter or as a means for positioning larger catheters.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use an imaging catheter including a drive cable similar to that of Pomeranz as the secondary device of a catheter system similar to that of Soltesz in order to position the catheter body at a target tissue site.

4. Claims 19 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soltesz ('925) in view of Pomeranz ('609) as applied to claims 11 and 27 above, and further in view of Cottenceau et al. ('424). Soltesz, as modified by Pomeranz, teach all of the limitations of the claims except that the intermediate tubular portion is adhesively bonded with the proximal and distal tubular portions. Cottenceau et al. teach a catheter having three regions of variable rigidity. The catheter is formed by adhesively or thermally bonding an intermediate tubular portion 33 to a proximal tubular portion 31 and a distal tubular portion 35, respectively. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to manufacture a catheter having three portions with variable longitudinal rigidity similar to that of Soltesz, as modified by Pomeranz by adhesively bonding the tubular portions coaxially

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in view of the teachings of Cottenceau et al. as an engineering design choice, simply substituting one known method of manufacturing such a catheter for another.

5. Claims 23, 24, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soltesz ('925) in view of Pomeranz ('609) as applied to claims 11 and 27 above, and further in view of Chow ('296). Soltesz, as modified by Pomeranz, teach all of the limitations of the claims except for that the length of the distal tubular portion is about 100-400 mm, and preferably 150 mm. Chow teaches a catheter having longitudinal regions of changing flexibility. The catheter includes a distal portion B that has an intermediate tubular portion **42** having a length **L5** of 50 to 150 mm and a distal tubular portion **44** extending to a distal end of the catheter body having a length **L6** of about 200 to 300 mm. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that the lengths of the proximal, intermediate and distal portions of a catheter similar to that of Soltesz as modified by Pomeranz could be selected within the range of those taught by Chow or otherwise as an engineering design choice to gradually alter the longitudinal flexibility of the catheter.

Response to Arguments

6. Applicant's arguments with respect to claims 11-13 and 18-38 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that the claims have been amended to recite a tubular catheter body comprising a single lumen so that the combination defines a vascular catheter and that the combination of limitations now claimed is not disclosed in the prior art of record. This argument is moot in view of the new grounds of

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rejection citing Soltesz and Pomeranz set forth hereinabove. Soltesz teaches an intravascular catheter having a single lumen for guiding a secondary catheter device and proximal, intermediate and distal portions with varying flexibility. Pomeranz teaches a guidewire imaging catheter including drive cable for rotating a work element of a imaging catheter, where the imaging catheter is adapted to be used as a means for positioning larger catheters.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

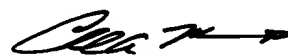
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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December 24, 2003